3738

PATENT
Attorney Docket No. 08442.0002-04000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Joseph C. Cauthen	Group Art Unit: 3738
Application No.: 10/085,040	Examiner: U. Chattopadhyay
Filed: March 1, 2002	Confirmation No.: 8078
For: INTERVERTEBRAL DISC ANNULUS STENT	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), applicant brings to the attention of the Examiner the information presented below and as attached hereto. This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of $180.00 as specified by Section 1.17(p).

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Dr. Cauthen's Abstract

On or about September 4, 1998, before the critical date (i.e., one year before the October 20, 1999 priority date of the present application), Dr. Cauthen prepared a draft abstract discussing his ongoing work in the area of spinal disc annulus repair, including some aspects of the present invention. The abstract was prepared to qualify Dr. Cauthen to present a poster at the Spine and Peripheral Nerves Section of the Joint Meeting of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) in Orlando, Florida in February of 1999 ("AANS/CNS meeting"). A copy of this draft abstract is attached as Exhibit A. This abstract was first distributed to conference attendees in February 1999, which is after the critical date.

Dr. Cauthen hired a consultant in 1998 to help him collect patient data and to help him with his poster for the AANS/CNS meeting. As a result of the ongoing development of Dr. Cauthen's technique as data was gathered and operations were performed, and the application of proper clinical data collection and analysis, Dr. Cauthen was able to present conference attendees in February 1999 with an updated results panel (Exhibit B), showing data assembled after the abstract was first submitted.

Dr. Cauthen, in the final line of his abstract, as published, states his conditional assessment of his surgical techniques, writing that microsurgical annular reconstruction "may prove" valuable as the technique "continues to evolve."

Dr. Cauthen's Continued Surgical Practice

Dr. Cauthen continued to perfect his invention and technique by performing surgeries using aspects of the claimed invention consistently from the period following the submission of the abstract on September 4, 1998 until the critical date (October 20, 1998). Records were kept, patients were monitored, and Dr. Cauthen retained control of the invention throughout this time period. He advised patients that he was going to use an additional procedure during surgery, that it was an experimental procedure (or words to that effect), and that he was not charging them for the time and effort involved in performing the procedure, i.e., there was no charge over the usual fees for the conventional herniated disk surgery.

No Commercial Public Use

Dr. Cauthen's disclosure to patients of his technique does not create a bar to patenting. *T.P. Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965 (Fed. Cir. 1984) (Exhibit C), quoting the Supreme Court in *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126, 136 (1877), which held that, "It is not public knowledge of his invention that precludes the inventor from obtaining a patent for it, but a public use or sale of it." 724 F.2d at 970. In this case, there is a confidential and privileged doctor-patient relationship between Dr. Cauthen and his patients. Additionally, Dr. Cauthen's technique was completely internal in the body and not visible after surgery. Even if these aspects were not present in this case, the use of the invention in public does not create a public use where that usage is in the nature of experimentation. See *id.* at 970-71.

Not Ready for Patenting Before the Critical Date

In order to show the efficacy of the invention and that it would work for its intended purpose, the collection of patient follow up data was required. These data were subject to analysis by accepted means, including among other things, adequate sample size (number of procedures), and comparison to a control group (patients undergoing standard treatment). Dr. Cauthen did not possess this information until after the critical date. The invention was therefore not ready for patenting before the critical date *See Pfaff v. Wells Electronics Inc.*, 525 U.S. 55, 48 USPQ2d 1641 (1998) (Exhibit D).

Conclusion

Because Dr. Cauthen's invention was not the subject of commercial public use, nor was it ready for patenting before the critical date, there are no grounds for rejection of the invention based on the information presented here.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the attached documents are material or constitute "prior art." Applicant believes, for at least the reasons set forth herein, that the attached information does not constitute "prior art" under United States law. Applicant reserves the right to present to the Office the relevant facts and law regarding the appropriate status of the information submitted herein.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the information submitted herein, should any of this information be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: April 18, 2005

By: _____
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